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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,103	10/22/2003	Russell Reeve	9062-27	4763

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EXAMINER

BARAN, MARY C

ART UNIT	PAPER NUMBER
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2857

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,103	Applicant(s) REEVE ET AL.	
	Examiner Mary Kate B. Baran	Art Unit 2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7,12-17 and 21-34 is/are rejected.
- 7) ☒ Claim(s) 3,6,8-11,18-20 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 32 is rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Claim 32 teaches "computer program code" which is configured to perform specific functions; however, this code is not stored on a computer readable medium, which would allow it to run.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 7, 12-17 and 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunkel (U.S. Patent No. 5,572,125) in view of Durkin et al. (U.S. Patent No. 6,721,583) (hereinafter Durkin) and further in view of Otvos (U.S. Patent No. 4,933,844).

Referring to claims 1, 2, 4, 5, 12-15, 21-26 and 32-34, Dunkel teaches measuring constituents in a subject (see Dunkel, column 13 lines 37-52), comprising: an NMR spectrometer for acquiring an NMR composite spectrum of a sample (see Dunkel,

column 23 lines 15-18); defining a plurality of individual NMR constituent spectrums, each associated with a selected reference constituent signal lineshape (see Dunkel, column 23 lines 22-29), each constituent spectrum having associated spectra that contribute to the composite NMR spectrum of the (see Dunkel, column 23 lines 30-39); generating a design matrix of the selected individual constituents, the design matrix including data sets for each of the plurality of individual constituents in a spectrum of interest, each individual selected constituent data set including amplitude values of its associated spectral lineshape, wherein a plurality of the selected individual constituents are closely correlated with overlapping signal lineshapes in the spectrum of interest (see Dunkel, column 23 lines 50-65).

Dunkel further teaches obtaining a composite signal of a target sample undergoing analysis and generates a composite matrix of amplitude values of the lineshape of the composite signal in the spectrum of interest, the target sample comprising spectra from a plurality of the selected individual constituents that contribute to the composite signal (see Dunkel, column 23 lines 50-65); generating a reduced design matrix (see Dunkel, column 27 line 65 – column 28 line 31); computing regression fit weighting coefficients based on the design matrix (see Dunkel, column 14 lines 33-40), the reduced matrix, and the composite matrix to deconvolve the spectral contribution of at least one non-target variable across the spectrum of interest in the composite signal (see Dunkel, column 27 line 65 – column 28 line 31); applying a sequential least squares analysis to the regression fit weighting coefficients to restrain negative coefficients to zero (see Dunkel, column 23 line 66 – column 24 line 28);

determining a calculated composite lineshape based on the weighting coefficients (see Dunkel, column 25 line 53 – column 26 line 4).

Dunkel does not teach rotating the matrix and determining the concentrations of the constituents in the sample undergoing analysis or measuring the lipoproteins in a blood plasma or serum sample.

Durkin teaches rotating the matrix and determining the concentrations of the constituents in the sample undergoing analysis (see Durkin, column 7 lines 29-39).

Otvos teaches measuring the lipoproteins in a blood plasma or serum sample (see Otvos, column 1 lines 7-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Dunkel to include the teachings of Durkin because rotating the matrix would have allowed the skilled artisan to relate the spectra to the concentrations (see Durkin, column 7 lines 29-39), and to further include the teachings of Otvos because measuring the lipoproteins in a blood plasma or serum sample would have allowed the skilled artisan to determine the cholesterol level in the blood (see Otvos, column 1 lines 7-13).

Referring to claims 7, 16 and 17, Dunkel and Otvos teach all the features of the claimed invention except Durkin teaches that the design matrix includes columns and rows of data, wherein the number of columns in the design matrix corresponds to the number of different individual constituents of interest plus at least one additional column representing spectra contributions from at least one non-relevant variable.

Durkin teaches that the design matrix includes columns and rows of data, wherein the number of columns in the design matrix corresponds to the number of different individual constituents of interest (see Durkin, column 7 lines 39-45) plus at least one additional column representing spectra contributions from at least one non-relevant variable (see Durkin, column 7 lines 9-22).

It would have been obvious to one of ordinary skill in the art to modify Dunkel and Otvos to include the teachings of Durkin because having rows and columns corresponding to the number of individual constituents would have allowed the skilled artisan to accurately predict the concentrations of the of the unknown spectra (see Durkin, column 7 lines 50-62).

Referring to claim 27, Dunkel and Durkin teach all the features of the claimed invention except that the reference spectra for the plurality of lipoprotein constituents includes spectra for a plurality of different lipoprotein subclasses.

Otvos teaches that the reference spectra for the plurality of lipoprotein constituents includes spectra for a plurality of different lipoprotein subclasses (see Otvos, column 3 lines 24-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Dunkel and Durkin to include the teachings of Otvos because determining spectra for a plurality of different lipoprotein subclasses would have allowed the skilled artisan to determine the concentration of the lipoproteins (see Otvos, column 3 lines 48-52).

Referring to claim 28, Dunkel and Durkin teach all the features of the claimed invention except producing a customized subject report listing the concentrations of the lipoprotein constituents present in the sample.

Otvos teaches producing a customized subject report listing the concentrations of the lipoprotein constituents present in the sample (see Otvos, column 2 lines 58-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Dunkel and Durkin to include the teachings of Otvos because generating a report would have allowed the skilled artisan to print out of the lipoprotein concentrations (see Otvos, column 2 lines 58-61).

Referring to claims 29-31, Dunkel and Otvos teach all the features of the claimed invention except obtaining an internal reference signal and comparing the reference spectra and the sample spectra based on the internal reference signal, wherein the internal reference signal is derived from at least one NMR resonance peak produced by lactate and/or glucose.

Durkin teaches obtaining an internal reference signal and comparing the reference spectra and the sample spectra based on the internal reference signal (see Durkin, column 6 lines 1-18), wherein the internal reference signal is derived from at least one NMR resonance peak produced by lactate and/or glucose (see Durkin, column 6 lines 51-62).

It would have been obvious to one of ordinary skill in the art to modify Dunkel and Otvos to include the teachings of Durkin because detecting resonance peaks would have allowed the skilled artisan to observe metabolic concentrations (see Durkin, column 6 lines 54-56).

Allowable Subject Matter

3. Claims 3, 6, 8-11, 18-20 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McGahan teaches measurement of diffracting structures using one-half of the non-zero diffracted orders.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Kate B. Baran whose telephone number is (571) 272-2211. The examiner can normally be reached on Monday - Friday from 9:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (571) 272-2216. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17 March 2006



CAROL S.W. TSAI
PRIMARY EXAMINER